

**Department of Health Professions**

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# **Virginia Board of Pharmacy Law Update**

**DEA Pharmacy Diversion Awareness  
Conference**

**November 19 & 20, 2016**

**Caroline Juran, Executive Director**



# Disclosures

- No real or apparent conflicts of interest that may have a direct bearing on the subject matter of this continuing education program
- No financial relationships or commercial interest that needs to be disclosed
- Speaking to you today as the executive director of the Board of Pharmacy.



# Current Board Members

- Rebecca Thornbury, Chairman
- Ryan K. Logan, Vice-Chairman
- Jody H. Allen
- Melvin L. Boone (citizen)
- Freeda Cathcart (citizen)
- Michael Elliott
- Sheila Elliott
- Rafael Saenz
- Ellen B. Shinaberry
- Cynthia Warriner



# Objectives

- Briefly review select pharmacy-related bills passed by 2016 General Assembly
- Overview of recently enacted regulations and pending regulatory action
- Briefly explain 2017 legislative proposals
- Provide information on miscellaneous topics and reminders



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# New Laws Passed in 2016 General Assembly



# HB 528 - 3PL, Track and Trace, etc.

- Requires wholesale distributors to comply with federal track and trace requirements
- Creates new licensing category for in-state third party logistic providers and nonresident manufacturers
- Clarifies that manufacturers may distribute drug without an additional license as a wholesale distributor
- Clarifies in §54.1-3410.2 the use of bulk drug substances in compounding



# **HB 527 - Nonresident Medical Equipment Suppliers**

- Creates new licensing category for non-resident medical equipment suppliers
- Formalizes the Board's existing process and holds out-of-state MES facilities to similar licensure oversight as in-state MES facilities



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# HB 293/SB 513 – PMP *(Until July 1, 2019)*

- Expands mandatory requests to the PMP
  - §54.1-2522.1; Prescriber or delegate, at time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than 14 consecutive days
  - Physicians with DATA 2000 waiver IDs must query PMP prior to or as a part of execution of a treatment agreement with the patient





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# HB 293/SB 513 – PMP *(Until July 1, 2019)*

- Exceptions:
  - Patient receiving hospice or palliative care;
  - Treatment for surgical or invasive procedure and such prescription is not refillable;
  - Prescribed during inpatient hospital admission or at discharge;
  - Patient in nursing home or assisted living facility that uses a sole source pharmacy;



# HB 657 - PMP

- §54.1-2523.1; PMP advisory panel/disclosure
- DHP Director to develop, in consultation with advisory panel (representatives of Boards of Medicine and Pharmacy) criteria for:
  - indicators of unusual patterns of prescribing or dispensing;
  - misuse of covered substances; and
  - method for analysis of data collected by PMP using the criteria
- Unusual prescribing or dispensing to be disclosed to DHP Enforcement Division



# SB 287 -PMP

- §54.1-2521; Increased frequency for reporting
- Dispensers as of January 1, 2017 must report within 24 hours or next business day, whichever comes later



# SB 701- Pharmaceutical Processors

- Authorizes licensing of a pharmaceutical processor to cultivate, produce, and dispense cannabidiol oil and THC-A oil for treatment of intractable epilepsy
- Must have pharmacist-in-charge
- Board adopted emergency regulations
- Bill must be reconsidered by GA in 2017 prior to enactment of law or regulations



# 2017 Legislative Proposal

(Adopted by Board, but will NOT be included in 2017 Governor's Packet)



# PTCB Legislative Proposal

- Would have:
  - required PTCB for initial registration as a pharmacy technician
  - Grandfathered existing pharmacy technicians
  - Had a delayed effective date of July 1, 2018



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# Virginia General Assembly Legislative Information System

- <http://leg1.state.va.us/>
- Can search and track any bill by bill number, subject, or patron



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# Recently Enacted Regulations





# Licensing of Physician Dispensing Location

- Emergency regulations effective 12/7/15-6/6/17
- Authorizes Board to license facility from where physicians are dispensing
- Board currently working on permanent regulations
- Public hearing on 12/12/16



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# Licensing of Outsourcing Facilities/Compounding

- Emergency regulations effective 12/7/15 through 6/6/17
- Creates new licensing category
- Compliance with cGMPs and federal law
- Require pharmacy permit also when dispensing patient-specifically
- Public hearing for permanent regs on 12/12/16



# Scheduling of Drug

- Several actions to place various illicit drugs into Schedule I via Regulation
- Descheduled after 18 months unless law passed to permanently place into Schedule I
- Public hearing on 12/12/16



# Pending Regulatory Activity (not yet final)



# Periodic Regulatory Review

- Chapters 20 and 50
- Most recent comment period ended 8/10/16
- Next step = Board to draft proposed language
- Regulation Committee Meeting – November 29
- More opportunities to comment in future!



# 18VAC110-20-25 Coupons

- Would prohibit incentives to transfer prescription
- Would be unprofessional conduct to advertise or solicit in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing the transfer of a prescription absent professional rationale by use of coupons, rebates, or similar offerings.
- Public hearing on 12/12/16



# 18VAC110-20-110 Hours Worked

- Would state “Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day
- and shall allow at least six hours of off-time between consecutive shifts.
- A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.”
- Final regs in Governor’s office



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# Miscellaneous Topics



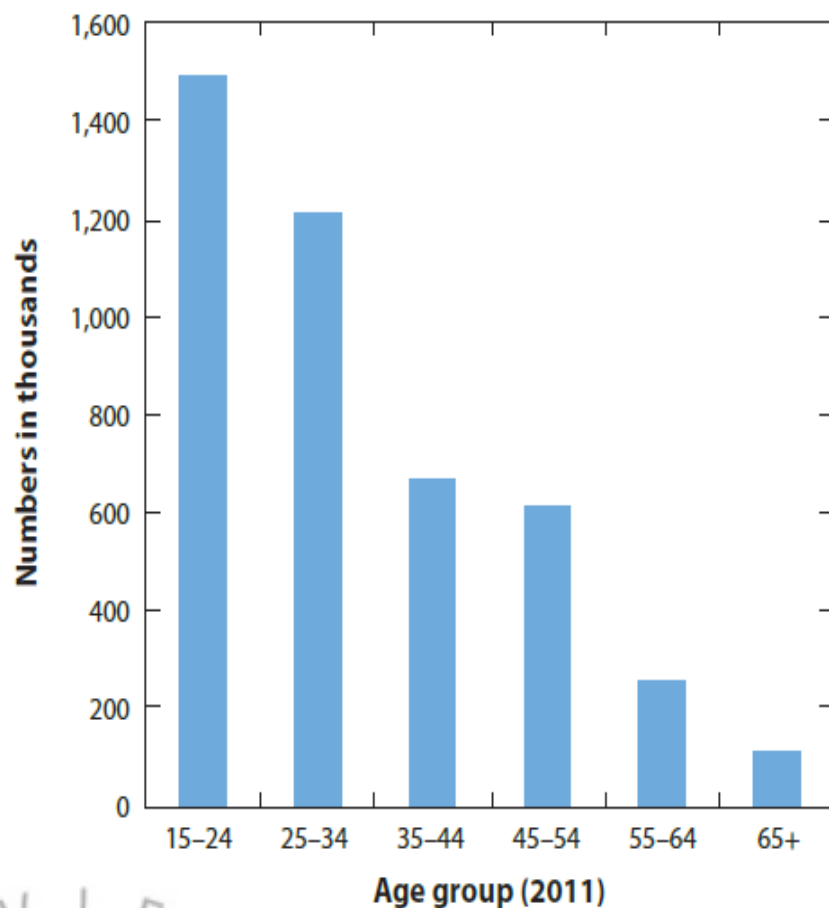


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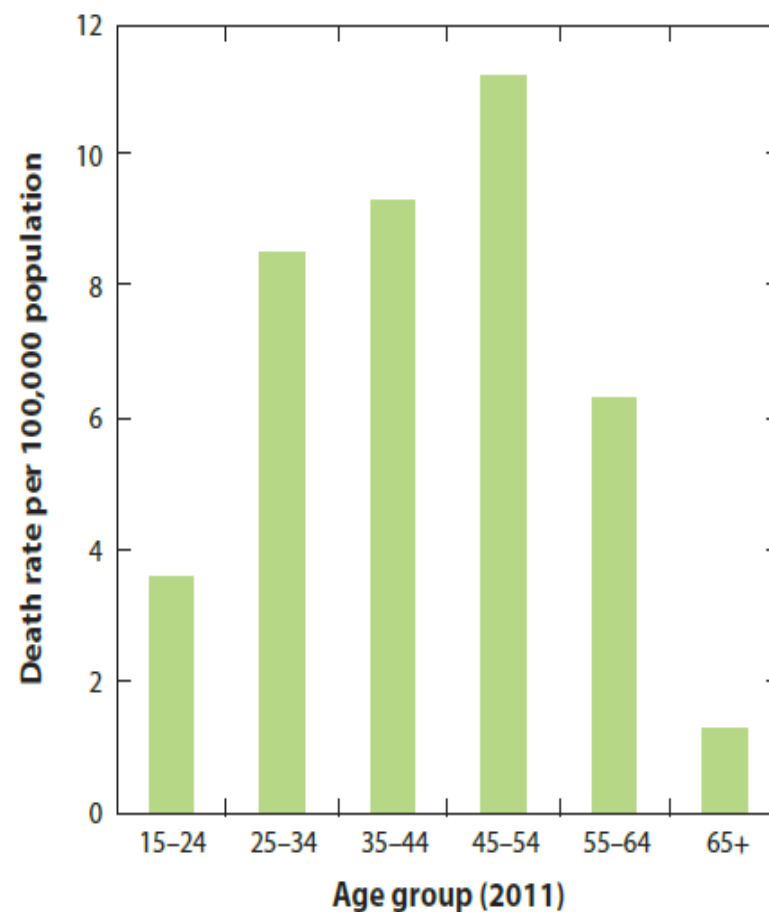
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# Opioids

**a** Past month nonmedical OPR use by age



**b** OPR-related unintentional overdose deaths by age



**Figure 4**

(a) Past month nonmedical OPR use by age versus (b) OPR-related unintentional overdose deaths by age. Abbreviation: OPR, opioid pain reliever. Sources: 58, 68.

From *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction* (Annu.Rev.Public Health 2015.36:559–74)

OPR – opioid pain reliever



# Opioid Statistics in Virginia

- Fatal overdoses during the first half of 2016 has increased 35% compared to same time period of 2015
- By the end of 2016, number of fatal opioid overdoses is expected to increase by 77% compared to 5 years ago.
- Number of emergency department visits for heroin overdose between Jan and Sept 2016 increased 89% compared to same time period 2015.



# Increased Access to Naloxone

- REVIVE! naloxone program
- § 54.1-3408 X authorizes pharmacist to dispense naloxone pursuant to oral, written, or standing order in accordance with protocol approved by BOP, in consultation with VDH and BOM
- Law enforcement and fire fighters may possess and administer; provides immunity



# Increased Access to Naloxone

- Board-approved protocol requires:
  - Standing order issued to pharmacy, signed by physician, good for up to 2 years
  - Pharmacist to counsel unless pharmacist is able to verify successful completion of REVIVE! training program
  - Labeling, but do not have to include person's name on the label
  - Dispensing brochure must be provided-  
<http://www.dhp.virginia.gov/pharmacy/>



# Inside Diversion

- Diversion by staff
- Pharmacy technicians
- Pharmacists



# External Diversion

- Use professional judgment to determine prescription validity, taking “red flags” into consideration
  - Prescriptions received in Virginia pharmacies from out of state prescriber and patient resides in a third state
  - Upon return, out of state patient brings friends
  - Paying cash
  - Justifies travel by saying your pharmacy has cheaper prices
  - Sleeping in car waiting for pharmacy to open



# “Red Flags”

- June 2012 Board e-newsletter article
- Red Flags video at <http://www.dhp.virginia.gov/pharmacy/>





# Internal Diversion

- Diversion by staff
  - Pharmacy technicians
  - Pharmacists
- Guidance Document 110-27



# Suggested Best Practices

- Perform state and federal criminal background checks on those with access to drugs
- Require periodic urine drug screening
- Prohibit staff from bringing bags into Rx dept
- Prior to leaving, routine bag and smock checks
- Routinely review policies and procedures to prevent, identify, address internal and external theft
- Do not delegate management of inventory to solely one individual
- Review drugs received, drugs dispensed, monitor for adjustments or excessive ordering
- Install surveillance cameras



# License Verifications

- Check License Lookup when hiring new pharmacists and pharmacy technicians
- Working for up to 9 months while enrolled in pharmacy technician training program only valid prior to initial registration
- Include questions on application regarding felony or misdemeanor convictions, pending charges, board action or pending disciplinary action



# Most Commonly Cited Deficiencies with Automatic Monetary Sanction

1. # 15: Perpetual Schedule II inventory
2. # 14: Incoming PIC inventory
3. # 20a: Pharmacist not documenting final verification of non-sterile compounding
4. # 12: Storage of prescription drugs outside previously approved drug storage area
5. # 20: Pharmacist not checking and documenting repackaging and bulk packaging



# Counterfeit Drugs

- Ensure prescription drugs are purchased only from properly licensed entities
- Verify licensure through License Lookup at Board's website – [www.dhp.virginia.gov](http://www.dhp.virginia.gov)
- .pharmacy Generic Top Level Domain (gTLD) with National Association of Boards of Pharmacy (NABP)



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# REMINDERS



# Appriss PMP Clearinghouse

- New PMP software platform
- Must submit data to Appriss as of 11/30
- Dispensers must register with clearinghouse prior to 11/30
- Questions – (855) 482-4767



# Electronic Renewal Notification

- Provide current email addresses to Board
- Pharmacists and pharmacy technicians recently informed via email
- Paper notification will be mailed if not renewed by deadline identified in email





# Reminders for Pharmacy Technicians

- Must obtain 5 hours of board-approved CE annually!
  - Cannot carry over from year to year
  - Must be ACPE, CME Category 1, or a board of pharmacy-approved program
  - Register for NABP CPE Monitor ID number
  - Do not attest to having completed CE if you did not
  - May request one-time extension for obtaining CE, then for good cause only



# 2G to 3G-4G, Security Systems

- 2G Sunset December 31, 2016
- Affects GSM technology; CDMA not affected
- Actions:
  - Contact alarm company, determine if action needed
  - Change to circuit board – no inspection needed
  - Any other change – submit remodel application
  - Maintain documentation describing technology in place, if upgrade necessary, and when it occurred



# Board E-newsletters

- Recent publication = October 2016
- Next publication = December 2016
- Available at <http://www.dhp.virginia.gov/pharmacy> under “Newsletters and Presentations”
- Published 3-4 times annually
- Notification of current publication via email



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QUESTIONS?